Karl Storz
Endoscopy-America, Inc.

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K010340

FEB 1 3 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document are accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe
Culver City, CA 90230
(310) 338-8100

Contact:

Marika Anderson
Senior Regulatory Affairs Specialist

Device Identification:

Common Name
Lithotriptor

Trade Name
Storz Modulith® Lithotriptor Model SLK

Indication: The Storz Modulith® Lithotriptor Model SLK is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

Device Description: The Storz Modulith® Lithotriptor Model SLK is a compact lithotripsy system comprised of a therapy source mounted on an articulating arm, an X-ray system, a patient stretcher and the Lithotrack® targeting system. The body contact material has a long history of use for medical devices and does not present any new issues of safety and effectiveness.

Substantial Equivalence: The Storz Modulith® Lithotriptor Model SLK is substantially equivalent to the Storz Modulith® Lithotriptor Model SLX since the basic features, design and intended uses are the same or similar. The minor differences in design, dimensions and features between the Storz Modulith® Lithotriptor Model SLK and the predicate device raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: Marika Anderson

Marika Anderson
Senior Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2001

Ms. Marika Anderson
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230-7600

Re: K010340
Storz Modulith® Lithotripter Model SLK
Received: February 5, 2001
Regulatory Class: II
21 CFR §876.5990/Procode: 78 LNS

Dear Ms. Anderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010340

Device Name: Storz Modulith® Lithotriptor Model SLK

Indications For Use:

The Storz Modulith® Lithotriptor Model SLK is indicated for use in the noninvasive fragmentation of urinary calculi in the kidney and upper ureter.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over -the-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices
510(k) Number K010340